REMARKS

1. Supplemental Interview Summary Record

Examiners Bertoglio and Kunz are thanked for according counsel a telephonic interview to discuss this case. The Interview Summary Record acknowledges that a "proposed claim was faxed and used for discussion purposes". If a copy of that proposed claim is required for compliance with 37 CFR §§1.2 and 1.133 and MPEP 713.04, we assume that Examiner Bertoglio will ensure that the fax is retained in the official file. We attach a courtesy copy.

In the interview, Counsel directed the Examiner's attention to examples 9, 10 and 14 of the written description training materials, in support of the hybridization and percentage identify limitation of the proposed claim.

The Examiners said that claim 1 would be allowable if the protein were limited to

(1) the protein encoded by SEQ ID NO:1, or

(2) "human SCCE" (without reference to a specific sequence"),

provided that we also limited the mammal to a mouse and the promoter to an SV40 promoter.

We did not discuss the final "wherein" clause of the proposed claim. However, it has been added in view of the office action, page 7, lines 8-10.

2. Election/Restriction

Claims 3 and 36-58 were withdrawn from consideration as being drawn to an unelected invention. Some of these claims have been cancelled. The remainder are now dependent, directly or indirectly, on claim 1. It is respectfully submitted that claim 1 qualifies as a linking claim, warranting rejoinder of the remaining unelected claims.

3. Description Rejection

3.1. The principal rejection is directed to an alleged lack of "written description" for claims which (1) define the SCCE-encoding nucleic acid based on hybridization to the complementary sequence to SEQ ID NO:1 or 3, or (2) define the encoded protein on the basis of serine protease activity and comprising a particular partial amino acid sequence, serine protease activity further define the overall percentage identity of the encoded protein with SEQ ID NO:2 (OA pp).

This rejection is moot as the claims are no longer so defined. Indeed, we have followed Supervisory Patent Examiner Kunz' suggestion, and required the encoded protein to be a human SCCE. We believe that by the disclosure of SEQ ID NO:2, which comprises a mature human SCCE, we have disclosed a species within amended claim 1 which is representative of the genus there defined.

3.2. The rejection of claims 21 and 22 is moot as those claims have been cancelled.

4. Enablement

The Examiner previously conceded that the specification's "enabling for a transgenic mouse comprising a transgene comprising SEQ ID NO:1, or encoding SEQ ID NO:2, operably linked to an SV40 promoter wherein said mouse displays epidermal hyperplasia and hyperkeratosis and a mild cellular inflammatory reaction of the skin". Amended claim 1 differs from the conceded subject matter only in that it recites, as recommended at the interview, that the transgene comprises a sequence encoding a "human SCCE".

It therefore appears that the enablement rejection is moot.

The Examiner will note that we did not limit claim 1 to an SV40 early promoter because the Examiner conceded the allowability of "an SV40 promoter". (OA page 7, line 8). If the

Examiner believes that a limitation to SV40 early promoter is necessary, we authorize an examiner's amendment to this effect. However, we should not be charged additional extensions of time fees since the Examiner had not previously required limitation to SV40 early promoters.

The discussion of intron sequences on page 12 of the office action is inconsistent with the concession on page 7 that there is enablement for a transgene encoding SEQ ID NO:2. SEQ ID NO:2 may be encoded by a cDNA sequence, such as SEQ ID NO:3, which be definition completely lacks introns. It likewise is inconsistent with the PTO proposal, at the interview, that we simply claim DNA encoding human SCCE.

The Examiner has not made any independent showing that there is reason to believe that an expression of transgene comprising cDNA encoding human SCCE would not result in the claimed phenotype. The case is based solely on Applicants' speculations at P16, L34-36. Many proteins have been successfully produced in transgenic animals using just cDNAs. Thus, the general expectation in the art is that introns are not necessary. However, it is known in the art that introns can comprise regulatory sequences, and hence retention of introns can be "useful" in terms of increasing the efficiency of expression.

Respectfully submitted,

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Enclosure
-courtesy copy draft claim

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Art Unit: 1632
HANSSON, et al.	Examiner: BERTOGLIO, V.
Serial No.: 10/071,214	Washington, D.C.
Filed: February 11, 2002	Date: March 8, 2004
For: SCCE MODIFIED TRANSGENIC MAMMALS AND THEIR USE AS MODELS OF HUMAN DISEASES	Docket No.: HANSSON=3A Confirmation No.: 9275

DRAFT CLAIM FOR DISCUSSION PURPOSES

BY FACSIMILE (571-273-0725)
U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window, Mail Stop AF
Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202

Sir:

A transgenic mouse having integrated within its genome a nucleotide sequence comprising

(1) a heterologous nucleotide sequence coding for an enzyme having serine protease activity and comprising the partial sequence glycine-X_1-X_2-isoleucine-isoleucine-aspartate-glycine (SEQ ID NO:14) where X_1 is aspartate or glutamate and X_2 is lysine or arginine, which

a) hybridizes with the complementary sequence to the nucleotide sequence SEQ ID NO:1 under stringent hybridization conditions of 5-10°C under T_m, and/or

b) has a 95% sequence identity to SEQ ID NO:1, and/or

(2) a heterologous nucleotide sequence which encodes the same amino acid sequence as that encoded by the heterologous nucleotide sequence of (1), operably linked to a SV40 promoter that drives expression of said heterologous scce in skin, wherein

the mouse exhibits epidermal hyperplasia and hyperkeratosis and a mild cellular inflammatory reaction to the skin.

Respectfully submitted,

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